# PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To:

see form PCT/ISA/220

# PCT

## WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43*bis*.1)

Date of mailing
*(day/month/year)* see form PCT/ISA/210 (second sheet)

Applicant's or agent's file reference
see form PCT/ISA/220

**FOR FURTHER ACTION**
See paragraph 2 below

| International application No. | International filing date *(day/month/year)* | Priority date *(day/month/year)* |
|---|---|---|
| PCT/US2004/009044 | 26.03.2004 | 26.03.2003 |

International Patent Classification (IPC) or both national classification and IPC
B65D73/00, A61J1/03, B65D75/34

Applicant
LAVIPHARM LABORATORIES INC.

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☒ Box No. II Priority
- ☒ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☒ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA"). However, this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notifed the International Bureau under Rule 66.1*bis*(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of three months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA:

European Patent Office - P.B. 5818 Patentlaan 2
NL-2280 HV Rijswijk - Pays Bas
Tel. +31 70 340 - 2040 Tx: 31 651 epo nl
Fax: +31 70 340 - 3016

Authorized Officer

Pernice, C

Telephone No. +31 70 340-3084

**WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/US2004/009044

**Box No. I Basis of the opinion**

1. With regard to the **language**, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

   ☐ This opinion has been established on the basis of a translation from the original language into the following language , which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).

2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:

   a. type of material:

   ☐ a sequence listing

   ☐ table(s) related to the sequence listing

   b. format of material:

   ☐ in written format

   ☐ in computer readable form

   c. time of filing/furnishing:

   ☐ contained in the international application as filed.

   ☐ filed together with the international application in computer readable form.

   ☐ furnished subsequently to this Authority for the purposes of search.

3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

4. Additional comments:

**Box No. II Priority**

1. ☒ The following document has not been furnished:

   ☒ copy of the earlier application whose priority has been claimed (Rule 43*bis*.1 and 66.7(a)).

   ☐ translation of the earlier application whose priority has been claimed (Rule 43*bis*.1 and 66.7(b)).

   Consequently it has not been possible to consider the validity of the priority claim. This opinion has nevertheless been established on the assumption that the relevant date is the claimed priority date.

2. ☐ This opinion has been established as if no priority had been claimed due to the fact that the priority claim has been found invalid (Rules 43*bis*.1 and 64.1). Thus for the purposes of this opinion, the international filing date indicated above is considered to be the relevant date.

3. ☐ The International Searching Authority has not been able to consider the validity of the priority claim because a copy of the earlier application whose priority has been claimed was not available to the International Searching Authority at the time that the search was conducted (Rule 17.1). This opinion has nevertheless been established on the assumption that the relevant date is the claimed priority date.

4. Additional observations, if necessary:

**Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability**

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application,

☒ claims Nos. 9-50, 63-117

because:

☐ the said international application, or the said claims Nos. relate to the following subject matter which does not require an international preliminary examination *(specify)*:

☐ the description, claims or drawings *(indicate particular elements below)* or said claims Nos. are so unclear that no meaningful opinion could be formed *(specify)*:

☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

☒ no international search report has been established for the whole application or for said claims Nos. 9-50, 63-117

☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:

| | | |
|---|---|---|
| the written form | ☐ | has not been furnished |
| | ☐ | does not comply with the standard |
| the computer readable form | ☐ | has not been furnished |
| | ☐ | does not comply with the standard |

☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-*bis* of the Administrative Instructions.

☐ See separate sheet for further details

## Box No. IV Lack of unity of invention

1. ☒ In response to the invitation (Form PCT/ISA/206) to pay additional fees, the applicant has:

   ☐ paid additional fees.

   ☐ paid additional fees under protest.

   ☒ not paid additional fees.

2. ☐ This Authority found that the requirement of unity of invention is not complied with and chose not to invite the applicant to pay additional fees.

3. This Authority considers that the requirement of unity of invention in accordance with Rule 13.1, 13.2 and 13.3 is

   ☐ complied with

   ☒ not complied with for the following reasons:

   **see separate sheet**

4. Consequently, this report has been established in respect of the following parts of the international application:

   ☐ all parts.

   ☒ the parts relating to claims Nos. 1-8, 51-62

## Box No. V Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

| | | | |
|---|---|---|---|
| Novelty (N) | Yes: | Claims | 5, 51-62 |
| | No: | Claims | 1-4, 6-8 |
| Inventive step (IS) | Yes: | Claims | 51-62 |
| | No: | Claims | 5 |
| Industrial applicability (IA) | Yes: | Claims | 1-8, 51-62 |
| | No: | Claims | |

2. Citations and explanations

   **see separate sheet**

**Re Item III.**

**Re Item IV.**

The separate inventions/groups of inventions are:

Claims 1-8, 51-62

A device for holding an active agent-containing composition, the device comprising:
- a support substrate;
- a pattern of adhesive in contact with one side of the substrate; and
- an array of discrete film segments removably attached to the substrate by contact with the adhesive, each film segment including the active agent-containing composition.

A method for holding an active agent-containing composition, the method comprising:
- providing a substrate, one side of the substrate in contact with a pattern of adhesive;
- removably attaching a film including an active agent-containing composition to the substrate; and
- segmenting the film attached to the final support substrate into an array of discrete film segments.

Claims 9-50, 63-91

A device for holding a composition, the device comprising:
- a support substrate;
- an array of discrete film segments removably attached to the substrate, each film segment including the composition.
- a sealing material covering the array of discrete film segments, the sealing material reattachably adhering to one side of the substrate, and where a selected portion of the sealing material includes a non stick coating.

A method for holding a composition, the method comprising:
superposing a sealing material over the array of discrete film segments attached to the support substrate, the seling material including a non-stick coating on at least a portion of

the sealing material, and where the non-stick coating reduces adhesion between the surface of the sealing material and at least one film segment when the sealing material contacts the at least one film segment.

Claims 92-103

A method for holding an active agent-containing composition, the method comprising:
- providing a substrate;
- forming a plurality of blister cavities in the substrate
- covering the substrate with the active agent-containing composition film;
- displacing segments of the film into each blister cavity;
- removing the film unassociated with the film segments;
- superposing a sealing material in contact with the substrate and covering the film segments; and
- attaching the sealing material at a plurality of ponts where the sealing material and substrate are in contact.

Claims 104-111

A method for applying a composition in a dosage unit to a dermal surface of a patient comprising:
- providing the dosage unit including the composition on a side that is larger in area than the dosage unit;
- holding the substrate without touching the dosage unit;
- bringing the substrate towards the dermal surface of the patient to bring the dosage unit into contact with the dermal surface; and
- pressing against the substrate to apply the composition to the dermal surface.

Claims 112-117

A method for holding an active agent-containing composition, the method comprising:
- intermittently applying a solution containing an active agent-containing composition to a substrate; and
- drying the intermittently applied solution to form film segments that are removably

attached to the substrate

They are not so linked as to form a single general inventive concept (Rule 13.1 PCT) for the following reasons:

The common technical features between groups of inventions 1 and 2 to 5 are "a device for holding a composition, the device comprising: a support substrate and an array of discrete film segments containing such composition; and a method of holding a composition, the method comprising: providing a support substrate, removably attaching a film containing such a composition" as defined by claim 1 and 51. These features are known in the prior art, see document US6410048 (additionally see any other document in the Search Report).

The potential special technical features are,

for group of inventions 1 (claims 1-8, 51-62): a device comprising a pattern of adhesive in contact with one side of the substrate; and the array of discrete film segments removably attached to the substrate by contact with the adhesive. The method comprising, providing one side of the substrate in contact with a pattern of adhesive, the film being in contact with the adhesive, and segmenting the film attached to the final support substrate into an array of discrete film segments;

for group of inventions 2 (claims 9-50, 63-91): a comprising a sealing material covering the array of discrete film segments, the sealing material reattachably adhering to one side of the substrate, and where a selected portion of the sealing material includes a non stick coating. A method comprising superposing a sealing material over the array of discrete film segments attached to the support substrate, the sealing material including a non-stick coating on at least a portion of the sealing material;

for group of inventions 3 (claims 92-103): a method comprising forming a plurality of blister cavities in the substrate, covering the substrate with the composition film, displacing segments of the film into each blister cavity, removing the film unassociated with the film

segments, superposing a sealing material in contact with the substrate and covering the film segments and attaching the sealing material at a plurality of points where the sealing material and substrate are in contact;

for group of inventions 4 (claims 104-111): a method for applying a composition in a dosage unit to a dermal surface of a patient comprising: providing the dosage unit including the composition on a side that is larger in area than the dosage unit, holding the substrate without touching the dosage unit, bringing the substrate towards the dermal surface of the patient to bring the dosage unit into contact with the dermal surface, and pressing against the substrate to apply the composition to the dermal surface;

for group of inventions 5 (claims 112-117): a method comprising intermittently applying a solution containing an active agent-containing composition to a substrate, and drying the intermittently applied solution to form film segments that are removably attached to the substrate.

Furthermore the potentially special technical features solve entirely different problems.

The device and method in group 1 is provided with an array of film segments containing the composition which are attached to the substrate by an adhesive pattern and manufactured as a lamination of substrate, adhesive and discrete film segments. This solves the problem of having a simpler to manufacture package.

The device and method in group 2 is provided with a sealing material covering the array of discrete film segments and including a non-stick coating. This solves the problem of protecting the array of film segments from the environment and at the same time providing an easy to open package.

The method in group 3 comprises the additional steps of making a blister cavity, forming discrete film segments, from a large composition containing film, into the cavities and sealing the cavities with sealing material. The problem solved is that of having individual film containing cavities sealed off from the environment.

The method in group 4 solves an entirely different problem, namely that of applying a

composition in a dosage to the dermal surface of a patient.

The method of group 5 comprises the application of a composotion in the form of a solution and drying this solution to form discrete film segments on the substrate. This method solves the problem of separately applying a film to the substrate and then segmenting it to form discrete film segments.

Since the potentially special technical features of the groups of inventions are different and solve different problems, they cannot be considered as being the same or corresponding technical features in the sense of as required by Rule 13 of the PCT. Therefore group of inventions 1-5 do not form unity of invention.

**Re Item V.**

1 The following document is referred to in this communication:

D1 : US 6 410 048 B1 (FOTINOS SPIROS) 25 June 2002 (2002-06-25)
D2 : FR-A-2 709 288 (SIEMENS MATSUSHITA COMPONENTS) 3 March 1995 (1995-03-03)

2 INDEPENDENT CLAIM 1

2.1 The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claim 1 is not new in the sense of Article 33(2) PCT.
Document D1 discloses (the references in parenthesis applying to this document):

A device for holding an active agent-containing composition, the device comprising:
- a support substrate (3);
- a pattern of adhesive (4b) in contact with one side of the substrate; and
- an array of discrete film segments (2) removably attached to the substrate by contact with the adhesive, each film segment including the active agent-containing composition.

3 DEPENDENT CLAIMS 2-4, 6-8

Dependent claims 2-4, 6-8 do not contain any features which, in combination with the features of any claim to which they refer, meet the requirements of the PCT in respect of novelty (Article 33(2) and (3) PCT). See document D1 and the corresponding passages cited in the search report.

4 DEPENDENT CLAIM 5

Dependent claim 5 does not contain any features which, in combination with the features of any claim to which it refers, meets the requirements of the PCT in respect of inventive step (Article 33(2) and (3) PCT). See document D2 and the corresponding passages cited in the search report.

5 INDEPENDENT CLAIM 51

The document D1 is regarded as being the closest prior art to the subject-matter of claim 51, and shows (the references in parentheses applying to this document):

A method for holding an active agent-containing composition, the method comprising:
- providing a substrate (3), one side of the substrate in contact with a pattern of adhesive (4b);
- removably attaching a film (2) including an active agent-containing composition to the substrate

the subject-matter of claim 51 differs from this known method in that includes the further step of segmenting the film attached to the final support substrate into an array of discrete film segments.

The subject-matter of claim 51 is therefore new (Article 33(2) PCT).

The problem to be solved by the present invention may be regarded as segmenting the active agent-containing film into discrete film when attached to the substrate and not before. Thereby avoiding the additional step of attaching each individual film segment to the substrate.

6 DEPENDENT CLAIMS 52-62

Claims 52-62 are dependent on claim 51 and as such also meet the requirements of the PCT with respect to novelty and inventive step.